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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/535,888 | 03/27/2000 | George McBride | CARDIOBEAT-3 | 3981 |

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| EXAMINER | |
|---|---|
| QURESHI, SHABANA | |
| ART UNIT | PAPER NUMBER |
| 2155 | 7 |

DATE MAILED: 07/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PRE

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/535,888 | MCBRIDE ET AL. | |
| | Examiner | Art Unit | |
| | Shabana Qureshi | 2155 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed on 16 May 2003 have been fully considered but they are not persuasive for the following reasons:

Applicants argue that none of the references teaches or suggests the elements of "cardiovascular function," "to obtain or displaying cardiac function test data" and Finkelstein does not teach "the use of sensors disposed on a patient, cardiac monitoring of any kind or impedance measurements."

Examiner respectfully disagrees all of the allegations as argued. Examiner, in his previous office action, gave detail explanation of claimed limitation and pointed out exact locations in the cited prior art.

Examiner maintains that Finkelstein's use of remote monitoring system for asthma patients (see abstract), test data collection using network and/or Internet (column 4, lines 19 – 67) and periodically downloads software from central processing facility (column 5, lines 53 – 65) clearly teaches the claimed limitation as argued.

Applicants' argue that the prior art as applied do not teach or suggest all the limitations of claim 1 as cited by the examiner.

Examiner likes to point out that in the "Schering Corp. v. Geneva Pharmaceuticals Inc., 64 USPQ2d 1032 (DC NJ 2002) Decided August 8, 2002." In the above case it is concluded that the prior art **disclosure need not be express in order to anticipate**. Even if a prior art inventor does not recognize a function of his or her process, the process can anticipate if that function was inherent. To establish inherency,

the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and **that it would be so recognized by persons of ordinary skill. Inherence is not necessarily coterminous with the knowledge of those of ordinary skill in the art**. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previous unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. Insufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation.

Applicants' argue that none of the references cited by the Examiner are directed to **cardiovascular function** and **cardiac monitoring** of any kind or **impedance measurements**.

In response to Applicants' argument that the references fail to show certain features of Applicants' invention, it is noted that features upon which Applicant relies ("cardiovascular function, cardiac monitoring or impedance measurements") are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With respect to argument Finkelstein do not explicitly teach non-invasive cardiovascular function related test measurement data and impedance test measurement data as claimed.

This measurement data are being used for cardiovascular function that do not add any substantial element to the claimed invention.

It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to modifying data to be non-invasive cardiovascular function related test measurement data and impedance test measurement data since differences in type of data do not distinguish the invention in term of patentability.

See In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).

For the above reasons, Examiner believes that rejection of the last office action was proper.

***Claim R jections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 – 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 6,283,923 B1 issued to Joseph Finkelstein et al. ("Finkelstein").

With respect to claims 1 and 9, Finkelstein teaches a medical testing program (abstract);

coupling at least one sensor to a computer device, the at least one sensor being coupled to a patient (column 5, lines 12-28);

uploading the test measurement data to the server via a communications link (column 6, lines 1-6);

receiving response to test data from the server as a download from the server via the communications link on the computer device (column 6, line 50 – column 7, line 56); and

displaying the processed data (column 199, lines 38-42).

Finkelstein teach that the program is software installed on a computer device and periodically downloads software from server (see Figure 2 and column 5, lines 53 – 65), but does not explicitly state that downloading a medical testing program as recited. However, it would have been obvious to one of ordinary skill in the art to allow the software or medical testing program software to be downloaded via the Internet so that remote users may download the program to their computer device. The process of allowing a software program to be downloaded through the Internet is well known and common in the art. Finkelstein et al also do not explicitly state that the program is executed to obtain test measurement. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made that in order to run the program on a client device, the program must be executed. Finkelstein et al further teach that the test measurement data is sent to a physician so that the physician can analyze or evaluate the data. The physician then sends alerts or responses to the user. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the patient to view the measurement data as well as send the data to the data to a physician so that the patient would be able to review the data.

As to claims 2 and 3, Finkelstein do not teach execution of a multimedia instructional guide on the Internet device to instruct the patient in placement of the at least one sensor. However, it would have been obvious to one of ordinary skill in the art to provide instructions for placement of the sensor so that the remote user may utilize the sensor correctly. It is obvious and well known to provide instructions with medical devices such as the sensor in order that accurate data may be collected.

As to claims 4 and 5, the execution of a data verification program on the Internet device prior to uploading the test measurement data (column 6, lines 37-49).

As to claims 6 and 7, Finkelstein do not explicitly state the inclusion of an un-install feature of the medical testing device upon completion of a testing sequence or utilizing an encryption program to encrypt the test measurement data. However, un-install features and encryption programs are commonly well known in the art as being features of downloadable programs. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include an un-install feature and an encryption program so that the program does not unnecessarily occupy memory, and the measurement data may securely and confidentially be transmitted via the Internet, respectively.

As to claim 8, the storing the medical testing program in the device memory (column 5, lines 30-35).

As to claim 9, Finkelstein teaches storing a testing measurement portion of the medical testing program in the memory for execution (column 5, lines 30-35); storing a test diagnostic program portion of the medical testing program in the memory for

execution (column 6, lines 25-36; column 199, lines 43-64); storing a verification portion of the medical testing program in the memory for execution (column 6, lines 37-49).

Finkelstein does not explicitly state the inclusion of an un-install feature of the medical testing device upon completion of a testing sequence or utilizing an encryption program to encrypt the test measurement data. However, un-install features and encryption programs are commonly well known in the art as being features of downloadable programs. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include an un-install feature and an encryption program so that the program does not unnecessarily occupy memory, and the measurement data may securely and confidentially be transmitted via the Internet, respectively.

As to claim 10, downloading an impedance cardiography program as a part of said medical testing program (column 5, lines 53 – 65).

Subject matter of claims 11 and 12 are rejected in the analysis above in claims 1 – 9 and these claims are rejected on that basis.

***Conclusion***

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Contact Information***

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shabana Qureshi whose telephone number is (703) 308-6118. The examiner can normally be reached on Monday - Friday, 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hosain T. Alam can be reached on (703) 308-6662. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-7239 for regular communications and (703) 746-7238 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3900.

Shabana Qureshi
Examiner, AU 2155
July 21, 2003

HOSAIN T. ALAM
PRIMARY EXAMINER